

**510K) SUMMARY****DATE**

April 17, 2009

JUL 29 2009

X091197

**PRODUCT, CLASSIFICATION NAME**

Trade name: Planmeca ProSensor

Common name: Digital intraoral x-ray imaging system

Classification: 76 EHD, Class II

Regulation number: 872.1800

**MANUFACTURER**

Planmeca Oy

Asentajankatu 6

FI-00880 Helsinki, Finland

Phone: +358 20 7795 500

Fax: +358 20 7795 396

Contact person: Lars Moring

**UNITED STATES SALES REPRESENTATIVE (U.S. DESIGNATED AGENT)**

Planmeca USA Inc.

100 North Gary Avenue, Suite A

Roselle, IL 60172

Phone: (630) 529 2300

Fax: (630) 529 1929

Contact person : Bob Pienkowski

**INTENDED USE**

Planmeca ProSensor, digital intraoral x-ray imaging system, is an accessory to dental intraoral x-ray devices. It is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The device is digital, and the images are displayed on a monitor, and image manipulation, archiving and communication are performed via a computer. The device is to be operated and used by dentists and other legally qualified professionals.

**PRODUCT DESCRIPTION**

The Planmeca ProSensor is an accessory to the intraoral x-ray unit, and it captures the x-ray image with a sensor placed inside the patient's mouth. The digitized image is then sent either via Ethernet or a USB connection to a computer for viewing and archiving. The system consists of a sensor, a control box and a PoE (only needed for the Ethernet version).

**SUBSTANTIAL EQUIVALENCE**

We consider this new product to be similar in design, composition and function to the following device introduced into commercial distribution after May 28, 1976:

# K000428 Planmeca Dixi2

The comparison of characteristics supports substantial equivalence. Planmeca ProSensor is as safe and effective as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Planmeca Oy  
% Mr. Bob Pienkowski  
President  
Planmeca USA, Inc.  
100 North Gary Avenue, Suite A  
ROSELLE IL 60172

JUL 29 2009

Re: K091197  
Trade/Device Name: Planmeca ProSensor  
Regulation Number: 21 CFR 872.1800  
Regulation Name: Extraoral source x-ray system  
Regulatory Class: II  
Product Code: EHD  
Dated: June 26, 2009  
Received: July 1, 2009

Dear Mr. Pienkowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

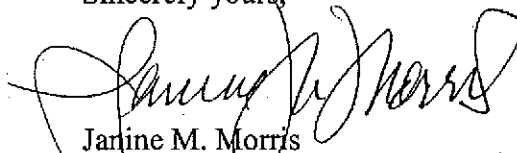
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jarline M. Morris". The signature is fluid and cursive, with the first name "Jarline" being more prominent.

Jarline M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K091197

Device Name: Planmeca ProSensor

Indications For Use:

Planmeca ProSensor, digital intraoral x-ray imaging system, is an accessory to dental intraoral x-ray devices. It is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The device is digital, and the images are displayed on a monitor, and image manipulation, archiving and communication are performed via a computer. The device is to be operated and used by dentists and other legally qualified professionals.

Prescription Use V  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K091197